REMARKS

Claims 1-4 and 6-12 were pending before the Office. Claim 5 was previously cancelled. Claim 7 is newly cancelled, but rewritten as new claim 13. Claim 8 is newly cancelled, but rewritten as new claim 16. Claims 1, 2, and 4 are newly amended. Claims 13-16 are new. Accordingly, claims 1-4, 6, and 8-16 shall be pending upon entry of this amendment.

No new matter is added by these amendments or newly added claims.

Applicants respectfully reserve the right to pursue any non-elected, canceled or otherwise unclaimed subject matter in one or more continuation, continuation-in-part, or divisional applications.

Applicants thank the Examiner for withdrawing the finality of the rejection and reopening prosecution on the merits as to claims 1 and 6-8. Applicants also acknowledge and thank the Examiner for withdrawing the prior objections to the specification and the objections to and rejections of the claims.

Reconsideration and withdrawal of the rejections of this application in view of the remarks herewith, are respectfully requested, as the application is believed to be in condition for allowance.

Priority

As stated in the Office Action, this application was filed under 35 U.S.C. § 371 as a National Phase application of International Application No. PCT/EP03/13281, filed November 26, 2003. The Examiner is thanked for acknowledging Applicants' entitlement to the benefit of the filing date of German application No. 10257354.9, filed December 9, 2002.

Withdrawn rejections

Applicants acknowledge and appreciate the withdrawal of the rejection of claims 1-3, 7 and 10 under 35 U.S.C. § 112, second paragraph (indefiniteness).

Applicants acknowledge and thank the Examiner for withdrawing the rejection of claims 1-6 and 7-10 under 35 U.S.C. § 101.

Objections are overcome

The Examiner objected to claim 1(d) for duplicating the sub-claim designator, "d)." Appropriate correction has been made to claim 1 to remove the redundant designator.

The Examiner objected to claim 7 as being an improper dependent claim for failing to further limit the subject matter of a previous claim. In accordance with the Examiner's suggestion, Applicants have canceled claim 7 and resubmitted it as new claim 13, thereby resolving the dependency objection.

Applicants note that since claim 8 was dependent on claim 7, claim 8 was cancelled and rewritten as new claim 16, which properly now depends on new claim 13.

Reconsideration and withdrawal of the above objections are respectfully requested.

The rejections under 35 U.S.C. § 112, first paragraph, are overcome

The Examiner has maintained the rejection of claims 1-3 and 6-8 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement for the reasons stated in the previous Office Action. Since claims 7 and 8 were cancelled, but rewritten as claims 13 and 16, respectfully, to overcome the above objection, this rejection applies to claims 1-3, 6, 13 (formerly claim 7) and 16 (formerly claim 8). The Examiner rejected each of Applicants' arguments made in the July 31, 2007 response, and concluded that written

description is not provided since the claims encompass "potentially large numbers of polynucleotides" and "polypeptides" which have not been shown to be in the possession of the Applicants. Applicants respectfully disagree with the rejection and traverse as follows.

As a traverse, Applicants assert that claim 1, and its dependent claims, 2, 3, 6, 13 (formerly claim 7) and 16 (formerly claim 8) do not lack written description when examined in light of the case law and Written Description Guidelines.

The Federal Circuit has addressed the standard for written description as it applies to the field of biotechnology in Regents of the University of California v. Eli Lilly and Co., 119 F.3d 1559 (Fed. Cir. 1997), stating that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. at 1567. The court further stated that "[a] definition by function [e.g. 'vertebrate insulin cDNA' or 'mammalian insulin cDNA'], as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is." Id. at 1568. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Addressing the manner by which a genus of cDNAs might be described, the court stated that "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit further clarified the written description requirement as it pertains to the field of biotechnology in Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316 (Fed. Cir. 2002). The court in Enzo stated that "**[t]he written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics...i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.**" Id. at 1324.

When the appropriate legal standard is applied to the instant claims and facts, the only conclusion to be made is that claim 1, along with its dependent claims, 2, 3, 6, 13 (formerly claim 7) and 16 (formerly claim 8), clearly meet the requirements for written description. The Examiner's particular rejection of claim 1 is directed at sub-part (c) and (d). The Examiner does not appear to reject sub-parts (a) or (b) of claim 1.

In particular, claim 1 recites an isolated nucleic acid molecule, selected from the group consisting of: (a) a nucleic acid molecule encoding a polypeptide having the amino acid sequence of SEQ ID NO: 2; (b) a nucleic acid molecule comprising the sequence of SEQ ID NO: 1; (c) a nucleic acid molecule which **encodes a fluorescent protein** and whose complementary strand **hybridizes under stringent conditions** with a nucleic acid molecule encoding the amino acid sequence of SEQ ID NO:2 or with a nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID NO:1; (d) and a nucleic acid molecule comprising a sequence which is at least **95% homologous to SEQ ID NO: 1** and which **encodes a fluorescent protein**.

Applicants respectfully submit that claim 1, in its entirety, including sub-parts (c) and (d), fully meet the Federal Circuit's standard for determining whether adequate written description is present. The standard requires that for a claim to have written description, the invention must be defined by **sufficiently detailed, relevant identifying characteristics**, which can include a **complete or partial structure coupled with a correlation between function and structure** of that which is claimed.

Here, claim 1, sub-part (c) defines a nucleic acid molecule which **encodes a fluorescent protein** and whose complementary strand **hybridizes under stringent conditions** with a nucleic acid molecule encoding the amino acid sequence of SEQ ID NO:2 or with a nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID NO:1. The structure of SEQ ID NO: 2 is expressly disclosed in the application, as is the nucleic acid sequence of SEQ ID NO: 1. Thus, their specific structures are well-defined. Because nucleic acid molecules which hybridize under stringent conditions to a defined sequence are expected to have complementary sequences, due to Watson-Crick pairing of nucleotide bases, their structures, too, are necessarily well-defined. In addition, the nucleic acid molecules of sub-part (c) must also encode a fluorescent protein. Like enzymatic activity, fluorescence of a protein can easily be tested and observed and is a functional property of such a protein. Since claim 1(c) couples complete or partial structure of the genus of nucleic acids together with a specific functional feature of the encoded proteins, the genus claim 1(c) clearly meets the written description requirements under Enzo.

A similar argument is easily made for claim 1, sub-part (d). Sub-part (d) defines a genus of nucleic acid molecules which **encodes a fluorescent protein** and which exhibit **at least 95% homology** with the nucleic acid of SEQ ID NO: 1. The structure of SEQ ID NO: 1 is expressly

disclosed in the application. Thus, its specific structure is well-defined. Because nucleic acid molecules which are 95% homologous to a defined sequence are expected to have highly similar nucleotide sequences, their structures, too, are necessarily well-defined. In addition, the nucleic acid molecules of sub-part (d) must also encode a fluorescent protein. Like enzymatic activity, fluorescence of a protein can easily be tested and observed and is a functional property of such a protein. Since claim 1(d) couples complete or partial structure of the genus of nucleic acids together with a specific functional feature of the encoded proteins, the claim 1(d) genus clearly meets the written description requirements under Enzo.

Regarding the rejection of claim 6, which defines a genus of proteins encoded by the nucleic acid molecules of claim 1, the subject matter defined by claim 6 does not lack written description because, as shown above, the genus of nucleic acids of claim 1 possesses sufficient written description.

Applicants now wish to address the particular assertions made by the Examiner.

In the July 31, 2007 Response, Applicants had pointed to Example 14 of the Written Description Guidelines as support for Applicants' position that claim 1(d) was supported by adequate written description. Applicants' maintain that Example 14 further supports Applicants' position that claim 1(d) meets the written description requirement. In Example 14, the contested claim is directed to a protein having a particular disclosed amino acid sequence and variants that are 95% identical to that sequence, and which have a particular enzymatic activity. In distinguishing claim 1 from Example 14, the Examiner argues that claim 1(d) lacks the "enzymatic activity" feature of the claim of Example 14. While claim 1(d) does not claim a particular enzymatic activity, it does require that the encoded protein be a **fluorescent protein**.

Enzo requires there to be a coupling between a **complete or partial structure and a function.** Nothing in Enzo requires that the "function" be an "enzymatic activity." Since fluorescence is also clearly a functional characteristic of a fluorescent protein, just is is an enzymatic activity would be, the Examiner should find the claim 1 meets the written description requirement, in analogy with Example 14. In addition, while the Examiner appears to imply that Example 14 is not pertinent to claim 1 because it's exemplary claim relates to a protein, instead of a nucleic acid molecule, Applicants wish to emphasize the Guidelines are not designed to duplicate every conceivable situation but rather are to provide general guidance. Here, Example 14 illuminates that it is the coupling of function with a structure that is important in meeting written description, which is, of course, consistent with the holding in Enzo.

A similar argument can be made to contest the Examiner's allegation that Example 9 of the Written Description Guidelines is not helpful in determining that claim 1, sub-part (c) meets the written description requirement. There, the Examiner argues that Example 9 differs from claim 1 because claim 1(c) does not require the nucleic acid molecules to encode proteins with the same "activity" as the protein encoded by SEQ ID NO: 1. While claim 1(c) does not claim a particular enzymatic activity, it does require that the encoded protein be a **fluorescent protein**. Enzo requires there to be a coupling between a **complete or partial structure and a function.** Nothing in Enzo requires that the "function" be an "enzymatic activity." Since fluorescence is also clearly a functional characteristic of a fluorescent protein, just as would be an enzymatic activity to an enzyme, the Examiner should find the claim 1 meets the written description requirement, in analogy with Example 9.

Accordingly, for at least the reasons above, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 1, and its dependent claims, 2, 3, 6, 13 (formerly claim 7) and 16 (formerly claim 8) under 35 U.S.C. 112, first paragraph.

On page 10 of the Office Action, the Examiner has newly rejected claim 9 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner contends that claim 9, which is drawn to a genus of antibodies which specifically bind to proteins encoded by any of the nucleic acids of claim 1, lack written description because of "the specification does not have a single example of an antibody which specifically binds to SEQ ID NO: 2 and certainly does not support possession of a genus of antibodies which specifically bind to the large genus of fluorescent proteins encompassed by claim 6." See page 11.

Applicants respectfully submit that written description for a genus of antbodies is found so long as the specification provides a well-defined antigen since antibody preparation and technology is routine in the art and is widely recognized as a mature field. On at least the basis of Example 16 of the Written Description Guidelines, which parallels the instant rejection, the Examiner is respectfully urged to reconsider and withdraw the rejection.

In Example 16, a claim directed to "an isolated antibody capable of binding to antigen X" is under consideration, i.e., a claim directed to "any antibody which is capable of binding to antigen X." The exemplary specification teaches and describes the structure of antigen X, but does not teach, describe or exemplify antibodies specifically binding to antigen X, or anything about their preparation. Nevertheless, the Example concludes that the claim does not lack

written description. The Example reasons that based on "the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature," the person having ordinary skill in the art "would have recognized that the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X." See pages 59-60 of the Written Description Guidelines.

Here, the genus of proteins of claim 6 are well characterized and defined. The claimed protein is defined in terms of a protein encoded by a nucleic acid which encodes SEQ ID NO: 2, a nucleic acid that is SEQ ID NO: 1, a nucleic acid which stringently hybridizes to SEQ ID NO: 1 or to a nucleic acid encoding SEQ ID NO: 2, and a nucleic acid which is at least 95% homologous to SEQ ID NO: 1. In each case, the encoded protein must be a fluorescent protein. Under Enzo, the genus of proteins under claim 6 do not lack written description because they are defined with a specific well-defined structure (amino acid and nucleic acid sequences of fluorescent proteins) coupled to a known correlation between function (fluorescence) and structure (amino acid and nucleic acid sequences of fluorescent proteins). Because the "antigen", i.e., the fluorescent proteins of claim 6, are well-characterized in this way, Applicants should be entitled to a claim, such as claim 9, directed to any isolated antibody which specifically binds any fluorescent protein of the invention. The same should hold for new claim 14, which is directed to an isolated antibody which specifically binds to the fluorescent protein of SEQ ID NO: 2.

Accordingly, reconsideration and withdrawal of the rejection of claim 9 are respectfully requested.

Claim 10 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking the requisite written description. In particular, the Examiner has alleged on grounds of new matter, that the method recited by claim 10 was not disclosed in the instant specification as originally filed. Applicants respectfully disagree with this rejection and traverse as follows.

By Applicant's July 31, 2007 Response, claim 10 was amended from reciting a "use of the fluorescent protein CGFP according to claim 1 to 7 as a marker gene and reporter gene," to instead recite:

> A method of determining whether a gene of interest, or fragment thereof, has been expressed comprising monitoring the fluorescence of a polypeptide encoded by a fusion gene and comparing it to the fluorescence when the gene or fragment is not expressed, wherein said fusion gene comprises the nucleic acid of claim 1 operably linked to said gene of interest, or fragment thereof.

Applicants respectfully submit that claim 10 in its entirety does not constitute new matter because the recited steps of the claim are merely conventional steps well-known in the art for using any fluorescent protein as a marker gene or reporter gene. In particular, it is well-known and highly conventional to couple through recombinant DNA techniques the expression of any gene of interest to monitor the expression level of that gene or the localization of the product of that gene within the dimensions of a cell or tissue. Indeed, the application states that "the use of fluorescent proteins has already been described previously" and cites to a number patents and published patent applications pertaining to the use of green fluorescent proteins from *Renilla mulleri* and *Aequoria*. The fusion genes recited by the claim, comprising a nucleic acid of claim

1 operably linked to a gene of interest, can readily be produced using conventional recombinant DNA techniques well-known in the art. The application discloses various recombinant DNA techniques, including the construction of translation fusions, in paragraphs 71 though 73 of the published instant application (2006/0188930). For at least the above reasons, claim 10 is not new matter. Beyond the use of the novel and unobvious nucleic acid sequences of claim 1, the remaining subject matter recited by claim 10 is either expressly or impliedly supported by the application and/or by conventional, well-known methods and techniques relating to the use of fluorescent proteins (and their corresponding nucleic acid molecules) as markers and/or reporters. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Claims 4 and 10-12 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking requisite written description. The rejection as to claim 10 was already addressed immediately above, and which, in view of Applicants' remarks is believed to be overcome. As to claims 4, 11 and 12, it is believed that since the rejection of base claim 1 for an alleged lack of written description has been overcome based on the Applicants' remarks herein, the rejection of claims 4, 11 and 12, which depend from claim 1 either directly of through an intervening claim, must necessarily be overcome. Applicants have already demonstrated that written description is provided for the genus of nucleic acid molecules of claim 1. It is respectfully submitted that the use of that genus of nucleic acid molecules with the recombinant vectors of claim 3, the host cells comprising such vectors of claim 4, the expression vectors of claim 11, and vectors with the inducible promoters of claim 12—all of which are described in the instant application and which

also constitute well-known tools and systems that are widely used in recombinant DNA technologies—constitutes claimable subject matter which clearly meets the written description requirement. The subject matter of claims 4, 11 and 12 merely couples the novel and unobvious nucleic acid sequences of the invention with the recombinant vectors, expression vectors, inducible promoters and host cells that are either described in the application or would be well-known to those skilled in the art. Clearly, since Applicants were in possession of the genus of nucleic acids of claim 1, they would also have been in possession of the subject matter of claims 4, 11 and 12.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 4, 11 and 12.

The rejections under 35 U.S.C. § 102(b), first paragraph, are overcome

Applicants thank the Examiner for withdrawing the rejection of claim 5 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S Patent No. 6,096,865 in view of the July 31, 2007 Response.

Applicants also thank the Examiner for withdrawing the rejection of claims 7 and 8 under 35 U.S.C. § 102(b) as allegedly being anticipated by Levine et al. ("Isolation and characterization of a photoprotein, "Phialidin", and a spectrally unique green-fluorescent protein from the bioluminescent jellyfish *Phialidium gregarium*," Comp. Biochem. Physiol., (1982), Vol. 72B, pp. 77-85) ("LEVINE") in view of the July 31, 2007 Response.

The Examiner has maintained the rejection of claim 6 under 35 U.S.C. § 102(b) as allegedly being anticipated by LEVINE. In particular, the Examiner contends that the green

fluroescent protein from *Phialidium gregarium* (alternatively known as, *Clytia gregaria*) disclosed by LEVINE is the same protein as the polypeptide defined by SEQ ID NO: 2 of the present invention. Applicants respectfully disagree with the rejection and traverse as follows.

The Examiner is respectfully pointed to the MPEP § 2131 which states that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). As further explained below, claim 6 is not anticipated by LEVINE because the green fluorescent protein of LEVINE is not, contrary to what is alleged by the Examiner, the identical protein of SEQ ID NO: 2.

The Examiner, in maintaining the rejection of claim 6, argued that "[e]ssentially, both the green fluorescent protein isolated by Levine and SEQ ID NO: 2 have the same fluorescence characteristics and are isolated from the same organism. The examiner, therefore, concludes that these are the same protein." See page 8, lines 17-19. Applicants respectfully submit that the Examiner is wrong and that the evidence suggests that SEQ ID NO: 2 is not the same protein as LEVINE's green fluorescent protein.

LEVINE did not provide a purified green fluorescent (see e.g., page 79, left column, lines 23-26), did not provide or determine the amino acid sequence of its green fluorescent protein, and did not provide the corresponding nucleic acid sequence. Since LEVINE does not disclose the exact structure of its green fluorescent protein, one of skill in the art cannot know with any certainty the exact structure and amino acid sequence of the protein. Moreover, is known that certain organisms express more than one fluorescent protein. The Examiner nevertheless concludes, based merely on similar but not identical excitation and emission profiles and on the

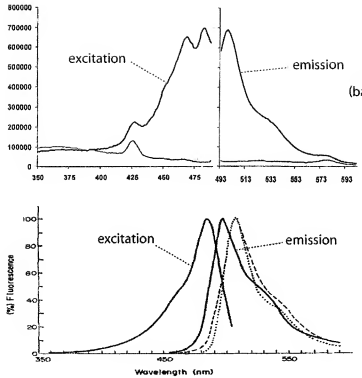
fact that SEQ ID NO:2 was obtained from *Clytia gregaria* (also known as *Phialidium gregarium*), that LEVINE's green fluorescent protein is SEQ ID NO: 2. Applicants submit that the evidence shows that, in fact, LEVINE's green fluorescent protein is not SEQ ID NO: 2.

First, the molecular weight of the green fluorescent protein of LEVINE ("*Phialidium* GFP" – see Fig. 3) is reported as 57,000±4% grams/mole. See page 80, column 1, lines 13-15. The molecular weight of the fluorescent protein of SEQ ID NO: 2 has been determined by Liu et al. ("Crystal structure of green fluorescent protein from Clytia gergaria at 1.55 A resolution," Protein Data Bank entry 2HPW, deposited July 17, 2006) to be 26,385.0 grams/mole. See the following websites:

http://www.pdb.org/pdb/explore/biologyAndChemistry.do?structureId=2HPW;

http://www.pdb.org/pdb/explore.do?structureId=2HPW. The disparate molecular weights of LEVINE's *Phialidium* GFP and SEQ ID NO: 2 demonstrate that *Phialidium* GFP and SEQ ID NO: 2 are not, in fact, the identical protein. Accordingly, LEVINE does not anticipate the instant claims.

Second, the excitation and emission spectra of SEQ ID NO: 2 are different from the excitation and emission spectra of LEVINE's *Phialidium* GFP. For ease of comparison, Applicants have prepare the below schematic ("Schematic 1") based on the excitation and emission spectra data of SEQ ID NO: 2 and LEVINE's *Phialidium* GFP:



The top portion of the schematic, labeled "APPLICATION," combines Fig. 4 (excitation) and Fig. 5 (emission) of the present application. The X and Y axes of Figs. 4 and 5 were adjusted to be approximately of the same scale. The bottom portion of the schematic, labeled "LEVINE," represents Fig. 3 of LEVINE (excitation and emission spectra of *Phialidium* GFP). Fig. 3 was scaled to approximately match the the scale of the X axis of APPLICATION figure (note that the dotted and dashed emission spectra of the LEVINE graph are emission spectra of other fluorescent proteins and are not relevant to the present comparison). By aligning Figs. 4 and 5 of the present application with Fig. 3 of LEVINE in this manner, the differences in the excitation and emission spectra of SEQ ID NO: 2 as compared to *Phialidium* GFP of LEVINE become immediately and plainly apparent. As can be seen, the excitation and emission spectra of SEQ

ID NO: 2 are not identical. In particular, the excitation spectrum of SEQ ID NO:2 shows a double-peak at the height of excitation, whereas the excitation spectrum of *Phialidium* GFP shows a single-peak at the height of excitation. In addition, the excitation spectrum of SEQ ID NO:2 shows a shoulder-peak at around 425 nm, whereas no such shoulder-peak is apparent for *Phialidium* GFP. The disparate excitation and emission spectra between of LEVINE's *Phialidium* GFP and SEQ ID NO: 2 demonstrate that *Phialidium* GFP and SEQ ID NO: 2 are not, in fact, the identical protein. Accordingly, LEVINE does not anticipate the instant claims.

Moreover, the Examiner even admits that the spectral characteristics of *Phialidium* GFP and SEQ ID NO: 2 are not identical. Indeed, the Examiner states that the excitation peak of SEQ ID NO: 2 is "slightly greater than 475 nm," as compared to maximum peak of 487 nm of LEVINE's *Phialidium* GFP. The Examiner further states that the peak of emission of SEQ ID NO: 2 is "slightly greater than 493 nm," whereas the emission spectra of *Phialidium* GFP "has a maximum of 497 nm." These disparate excitation and emission peaks stated by the Examiner, in addition to their disparate spectral profiles, would not suggest to one of ordinary skill in the art that the proteins exhibiting such different spectral characteristics were, in fact, the same proteins. Based on comparing the spectral characteristics of other non-*Phialidium* green fluorescent proteins to the spectral characteristics of *Phialidium* GFP, such a conclusion is not logical.

For example, the difference between the maximum excitation peaks of *Phialidium* GFP (487 nm) and the green fluorescent protein of *Aequorea aequorea* (400 nm – see page 81, Table 3 of LEVINE) is **13 nm**. The difference between maximum excitation peaks as between SEQ ID NO: 2 (475 nm) and *Phialidium* GFP (487 nm) is **12 nm**. The *Aequorea* protein is clearly not the same as LEVINE's protein because they are obtained from two entirely difference

organismal sources. Given that the excitation peak of SEQ ID NO: 2 is as different from the excitation peak of *Phialidium* GFP as is the excitation peak of the *Aequorea* protein to the excitation peak of *Phialidium* GFP, i.e., 12 nm versus 13 nm, respectively, Applicant does not understand how the Examiner could conclude that, on the basis of these spectral characteristics, SEQ ID NO:2 is the same protein as *Phialidium* GFP. If spectral characteristics—such as those relied on by the Examiner—could form that basis for determining whether two proteins were, in fact, the same proteins, then the Examiner might also conclude that *Phialidium* GFP and *Aequorea* GFP were the same, which is clearly not the true.

The Examiner's argument essentially relies on supposed inherency. The law of inherency dictates that a particular property (or particular protein in this case) is inherent only if it necessarily occurs in the prior art. *See Atlas Powder Co. v. Ireco Inc.,* 190 F.3d 1342, 1347 (Fed. Cir. 1990). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert,* 9 F.3d 1531, 1534 (Fed. Cir. 1993). The Board of Patent Appeals and Interferences has emphasized the "in relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

Here, LEVINE does not provide a purified green fluorescent protein, does not provide or determine the amino acid sequence of its green fluorescent protein, does not provide the corresponding nucleic acid sequence, and does not disclose any physical characteristics or properties—including the spectral characteristics of its protein—which would allow one of

ordinary skill in the art to conclude that LEVINE's protein necessarily must be SEQ ID NO: 2. Applicants respectfully submit that the Examiner must provide a basis in fact and/or technical reasoning which would reasonably support the determination that SEQ ID NO: 2 necessarily is the same protein as *Phialidium* GFP. As explained above, disparate molecular weights, nonidentical spectral characteristics, and the fact that the proteins were obtained from "the same organism" do not constitute sufficient evidence to meet this standard. Moreover, it is not inconceivable that this organism, *Clytia gregaria*, like other fluorescent protein-containing organisms, manufactures more than one fluorescent protein.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 6 under 35 U.S.C. § 102(b).

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the Examiner and SPE are respectfully requested; and, the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks made herein, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are respectfully requested. Please charge any required fee or credit any overpayment to Deposit Account No. 04-1105.

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